

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 10 MAY 2005



WIPO

PCT

Applicant's or agent's file reference C959ANT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/KR2003/002898</b>	International filing date (day/month/year) <b>30 DECEMBER 2003 (30.12.2003)</b>	Priority date (day/month/year) 23 JANUARY 2003 (23.01.2003)
International Patent Classification (IPC) or national classification and IPC  <b>IPC7 C12N 5/06, C12N 5/08, A61P 9/00</b>		
Applicant  <b>ANTEROGEN CO., LTD. et al</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the report
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  <b>13 AUGUST 2004 (13.08.2004)</b>	Date of completion of this report  19 APRIL 2005 (19.04.2005)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer  LEE, CHUNG HO Telephone No. 82-42-481-8160 

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/002898

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language: English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

PCT/KR2003/002898

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-5, 10-12	YES
	Claims	6-9	NO
Inventive step (IS)	Claims	1-5, 10-12	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

### 2. Citations and explanations (Rule 70.7)

The following documents have been considered for the purpose of this report:

D1: EP 1254952 A1 (KYOWA HAKKO KOGYO CO., LTD.) 6 November 2002

D2: WO 2002/083864 A2 (ANTEROGEN CO., LTD.) 24 October 2002

#### I. Novelty (Claims 6-9)

Claims 6-9 of the present application do not meet the requirement of PCT Article 33(2), since the subject matter of the claims is not novel over the prior art as defined in the Regulations (PCT Rule 64).

Claims 6-9 of the present application relate to a cell for transplantation into myocardial tissue of a mammal, which are produced by culturing bone marrow mesenchymal stem cells (BMSCs) under conditions that induce said cells to differentiate into cardiomyogenic cells.

D1 and D2 describe a cell having the potential to differentiate into cardiomyocytes of a mammal (e.g., a human) by culturing BMSCs and inducing said cells to differentiate into cardiomyogenic cells.

Therefore, D1 and D2 destroy the novelty of the subject matter of claims 6-9 of the present application.

#### II. Novelty and Inventive Step (Claims 1-5, 10-12)

Claims 1-5, 10-12 of the present application relate to a method for producing cells for transplantation into myocardial tissue of a mammal by culturing the BMSCs in a medium containing IGF-1 (Insulin-like Growth Factor-1) and a pharmaceutical composition for transplantation into myocardial tissue of a mammal diagnosed as having a disorder characterized by insufficient cardiac function, in order to treat the mammal using the same cells.

D1 and D2, which are considered to represent the most relevant state of the art, disclose a method for producing the same cells mentioned above. D1 discloses the use of 5-azacytidine as a cardiomyogenic cell-inducing agent and D2 discloses the use of BMP-2 or bFGF.

(Continued on Supplemental Box.)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/002898

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Continuation of Box V.

Compared with the present claims 1-5, 10-12, none of the above-mentioned prior art documents disclose the method for producing cells for transplantation into myocardial tissue of a mammal by using IGF-1 as a cardiomyogenic cell-inducing agent. In addition, the claimed invention is not considered obvious to a person skilled in the art by using the teachings of D1-D2.

Therefore, the subject matter of claims 1-5, 10-12 of the present application complies with the requirements of novelty and inventive step under PCT Article 33(2) and (3).

### III. Industrial Applicability

There is no reason for forming a negative opinion about the industrial applicability of this application. Consequently, claims 1-12 appear to meet the requirement of PCT Article 33(4).